

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Yu et al.
Appl. No.	:	10/802,153
Filed	:	March 17, 2004
For	:	SELF-EMULSIFYING COMPOSITIONS, METHODS OF USE AND PREPARATION
Examiner	:	Vickie Y. Kim
Group Art Unit	:	1618

DECLARATION UNDER 37 C.F.R. § 1.131

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

1. This declaration is to establish that the invention claimed in the above-captioned U.S. Patent Application was reduced to practice prior to November 2002.

2. We are the named inventors of the described subject matter and all claims in the above-captioned U.S. Patent Application Serial No. 10/802,153 (the '153 patent application), which was filed March 17, 2004 and claims priority to Patent Application Serial No. 10/392,375 filed March 18, 2003, titled "SELF-EMULSIFYING COMPOSITIONS, METHODS OF USE AND PREPARATION."

3. We are familiar with the prosecution history of the '153 patent application, including the amendment being filed along with the present Declaration.

4. We hereby declare that prior to November 2002, we reduced to practice self-emulsifying compositions and methods of use and preparation described and claimed in the '153 patent application.

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5. As evidence of reduction to practice, we attach herewith as Exhibit "A," a record of invention. Although the date on this document has been redacted, the date was prior to the November 2002 publication of the Goto reference cited by the Examiner. Prior to the first day of November 2002, we reduced to practice the invention claimed in the '153 patent application in the form of a flowchart, formulation ingredients labeled Samples 1-14 and experimental results showing the solutions' viscosities, osmolality, particle mean size and 99% cumulative size.

6. The record of invention (Exhibit A) shows that all of the limitations of Claims 1-3, 6-8, 10, 11, 15, 16 and 17 were reduced to practice prior to November 2002.

7. All of the limitations of Claim 1 are shown in the record of invention. For example, Sample 3 of the record of invention shows a self-emulsifying ophthalmic solution with oil globules having an average size of less than 1 micron dispersed in an aqueous phase (particle mean size of 0.14 μm). The globules contain a surfactant component containing 1 or 2 surfactants (Lumulse GRH-40), a polar oil component (castor oil) the combination selected to self-emulsify without homogenization and a chlorite preservative component (purite).

8. All of the limitations of Claim 2 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution where the surfactant has a hydrophobic portion with a first part oriented proximal to the aqueous phase that is larger than a second part of the hydrophobic portion of the surfactant component oriented toward the interior of the oil globule (Lumulse GRH-40).

9. All of the limitations of Claim 3 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution where the surfactant component has a surfactant with a first part of the hydrophobic portion that contains more atoms than the second part of the hydrophobic portion (Lumulse GRH-40).

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10. All of the limitations of Claim 6 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution where the oil component contains castor oil.

11. All of the limitations of Claim 7 are shown in the record of invention. For example, Sample 14 of the record of invention shows a solution with a compound having an ether, ester or amide formed from at least about 1 to 100 ethylene oxide units (TPGS (tocopherol polyethylene glycol succinate)) and at least one vitamin or vitamin derivative (Vitamin E acetate).

12. All of the limitations of Claim 8 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution with one surfactant that is Lumulse GRH-40.

13. All of the limitations of Claim 10 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution where the oil globules have an average particle size of less than 0.25 microns (particle mean size of 0.14 μm).

14. All of the limitations of Claim 11 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution where the oil globules have an average particle size of less than 0.15 microns (particle mean size of 0.14 μm).

15. All of the limitations of Claim 15 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution with a chlorite preservative that is a stabilized chlorine dioxide (purite).

16. All of the limitations of Claim 16 are shown in the record of invention. For example, line 5 of page 1 of the record of invention has an "X" next to "Multi-Purpose Sol'ns (MP):" indicating that the invention can be used as a multipurpose solution for contact lenses.

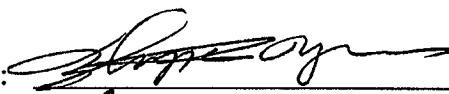
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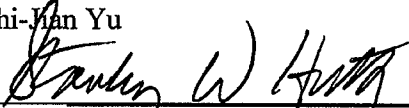
17. All of the limitations of Claim 17 are shown in the record of invention. For example, Sample 3 of the record of invention shows a solution with Lumulse GRH-40 and castor oil.

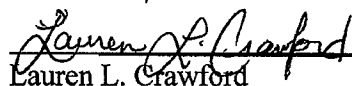
18. All of our acts leading to the reduction to practice of the subject matter claimed in the '153 patent application were performed in the United States of America.

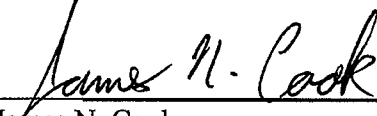
We declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent resulting therefrom.

Dated: August 30, 2007

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